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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,857	12/12/2001	Antonio Bosetto	02508.0090	5464

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EXAMINER	
BIANCO, PATRICIA	

ART UNIT	PAPER NUMBER
3762	6

DATE MAILED: 07/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/913,857	BOSETTO ET AL.	
	Examiner	Art Unit	
	Patricia M Bianco	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action*.

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. PCT/IB00/01895, filed on 12/18/00.

Receipt is acknowledged of certified copies of the papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The abstract includes the legal phraseology "comprising" which is improper and should be removed.

The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

3. The disclosure is objected to because of the following informalities: the specification does not include headings distinguishing the different sections.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
(e) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(f) BRIEF SUMMARY OF THE INVENTION.
(g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(h) DETAILED DESCRIPTION OF THE INVENTION.
(i) CLAIM OR CLAIMS (commencing on a separate sheet).
(j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Objections

4. Claims 1 and 7 are objected to because of the following informalities:

(i) in each claim, applicant uses the transition phrase "comprises" in multiple locations, lines 3 & 9 in each claim and since "comprises" is a transition phrase, it renders the claim confusing with respect to what is in the preamble and what is being positively recited as the body of the claim;

(ii) the claims begin with setting forth the invention to be a "Method for determining blood recirculation in a vascular access(11) of a patient" and then further recite, in lines 6-8, "the recirculation taking place in the vascular access between the return line (26) and the collecting line (24)." It is confusing because it first appears that the invention is to determine blood recirculation, but in the body it explicitly states where the recirculation is.

Clarification and correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 1 & 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Bellco (EP 0 693 297 A1). Bellco discloses a dialysis system and method that includes a means for determining the amount of blood circulation in the vascular access, or fistula, during treatment. Saline ions are infused into the blood system, causing a disturbance, which will inherently cause a transient state. The dialysis system has an electronic control system, including conductivity sensors for measuring saline ion concentration in the blood via electrical conductivity measurements, to determine the amount of blood recirculation by comparing the measurements before and after the saline induction.

6. Claims 1-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Cavicchioli et al. (6,537,240). Cavicchioli discloses a dialysis system comprising blood collection and return lines, a dialyzer (i.e. filter) and a computation and control unit for operating and monitoring the system and dialysis procedure, including the determination of blood recirculation. The system and procedure comprise the steps of inducing a variation (i.e. disturbance) in the blood line, which inherently induces a transient state. The variation may be caused by varying the ultrafiltration flow rate. The blood parameter affected is disclosed to be a change in hemoglobin concentration. See entire document.

7. Claims 1 & 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Krämer (5,866,015). Krämer discloses a method for determining hemodynamic parameters during extracorporeal hemotherapy. Blood is circulated through a circuit at a desired blood flow rate, said circuit including an arterial line, a venous line, a blood treatment unit (such as dialyzer) having multiple compartments, and a fistula connecting a patient to undergo treatment to the circuit. A blood parameter, such as a concentration of a blood constituent, flow or hematocrit, is measured using well-known measuring sensors. Multiple values are measured and the exact value is determined by a linear equation or extrapolation. A control unit alters the delivery rate of the blood pump, which inherently varies the ultrafiltration rate through the dialysis membrane. Thus, when the blood flow rate is varied by the system the ultrafiltration rate is also varied. The control system has a memory unit for storing the measured values and a processor unit to determine the measured value of the desired parameter. The processor arithmetically determines the actual value for the parameter by using the different or varied blood flow rates and the measured values. Krämer also discloses that there is no need to add an indicator solution for the measurements to be made.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application

> by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 2-6 & 8-12 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Krämer (5,866,015). Krämer substantially discloses the invention as claimed (see above) except for distinctly indicating that there disturbance induced causes a variation of, or a succession of changes, in the concentration of hemoglobin in the blood. It is the position of the examiner that Krämer inherently teaches taking multiple measurements of a blood parameter, which inherently includes at least one or a succession of variations of hemoglobin concentration as said parameter. It is also inherent that the measured parameter can be of hemoglobin since the disclosure sets forth measuring a concentration of a blood component. If applicant disagrees that the above measurements of hemoglobin concentration are not inherently taught by Krämer, then it would have been obvious to one having ordinary skill in the art to choose to make measurements of hemoglobin concentration variation to be used in the calculation as the desired parameter based on the design of a patient's treatment.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Keshavia, Krivitski, and Steuer et al. disclose analogous systems and methods for monitoring dialysis systems and procedures by making hemodynamic measurements of various blood parameters.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M Bianco whose telephone number is (703) 305-1482. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

June 25th, 2004

PATRICIA BIANCO
PRIMARY EXAMINER

Patricia M Bianco
Primary Examiner
Art Unit 3762